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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Thibaut Verjat

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OLIFF & BERRIDGE, PLC

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ALEXANDRIA, VA 22320-4850

EXAMINER

PANDE, SUCHIRA

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

08/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,986	Applicant(s) VERJAT, THIBAUT	
	Examiner SUCHIRA PANDE	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 10-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/19/06;6/30/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I invention (claims 1-9) in the reply filed on April 30, 2009 is acknowledged. The traversal is on the ground(s) that applicant has amended claim 15 to require "at least 15 nucleotide motifs" instead of "10 nucleotide motifs". Hence Brennan (US pat. 5,474,796 issued December 12, 1995) cited by Examiner to show Lack of Unity does not apply. This is not found persuasive because King et al. (1985) Science Vol. 229 no 4717: pp 974-976 teach a detection probe comprising at least 15 nucleotide motifs of a nucleotide sequence identified as SEQ ID NO 7 in the instant application. See alignment below where at least 20 nucleotides of SEQ ID NO 7 show 100% identity to nt 135 to 116 of probe MAC117 (see King et al. page 975 par. 3 and Fig. 4 where cloned probe of MAC117 are taught):

```
Query Match          100.0%;  Score 20;  DB 5;  Length 424;
  Best Local Similarity 100.0%;  Pred. No. 18;
  Matches 20;  Conservative 0;  Mismatches 0;  Indels 0;  Gaps
0;
```

```
Qy          1 GAGCCAGCCCGAAGTCTGTA 20  SEQ ID NO: 7
              |||||
Db          135 GAGCCAGCCCGAAGTCTGTA 116 MAC117 gene
```

Thus prior art taught a detection probe comprising at least 15 nucleotide motifs of SEQ ID NO 7. Thereby King et al. teach the amended claim 15 which recites—"A detection probe comprising at least 15 nucleotide motifs of a nucleotide sequence selected from SEQ ID No. 1 to SEQ ID No. 20". Hence the product of claim 15 lacks novelty as it was taught to one of ordinary skill in the art by prior art. Therefore Examiner has properly demonstrated that the product of group I invention lacks the same or corresponding special technical features of method of group II invention.

Furthermore, Applicant has cancelled the reference to Method of Breast cancer from all the pending claims thus rendering election of the two alternatives recited below moot.

- a. Method for Breast Cancer
 - i. Diagnosis of breast cancer
 - ii. Prognosis of breast cancer

Applicant has elected following species for examination:

- b. Target sequence gene (claims 1-4 are generic)
 - vi. HER2 (claim 5 in part)

Regarding election of species, Applicant also argues that Examiner has not demonstrated a lack of unity of invention in that claim, or, in other words, the distinct embodiments share no common subject matter that defines a contribution over the prior art. The 4 target sequence genes recited in claim 5 are different genes recognized in the art as such, hence by definition each one encodes for a different protein and thus structure of each gene (i.e. nucleotide sequence of each gene is different and hence the distinct embodiments (namely genes ESR1, ESR2, PGR and HER2) share no common subject matter that defines a contribution over the prior art.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Applicant has elected following SEQ IDs as part of restriction subgroup for examination:

- SEQ ID NO: 12 as the single detection probe;
- SEQ ID NOs: 7 and 8 as the two primers for the elected gene; and

-SEQ ID NOs: 27 and 28 as the two primers for the housekeeping gene;

2. Claims 10-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 30, 2009.
3. Currently claims 1-9 are active in the application and they will be examined to the extent they read upon the elected gene HER2 and elected SEQ ID NOs. 7, 8, 12, 27 and 28 in this action.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Certified copy of PCT/FR2004/050661 filed on December 7, 2004 has been received. Applicant is claiming priority to parent French application FR0314364 filed on 9 December 2003. However no certified English translation of the French application FR0314364 has been received so far. Hence, for purposes of prior art search, Examiner is considering the filing date of the PCT/FR2004/050661 i.e. December 7, 2004 as the priority date for instant filed application.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 5/19/2006 and 6/30/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

6. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figure I is labeled in French. The labeling of the above figure should be in English. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Interpretation

7. Claim 1 as currently recited states in preamble that it's a method for predicting a response of a patient to a treatment for breast cancer. None of the active steps recited in the method indicate how the detection of an amplicon correlates to predicting a response of a patient to a treatment for breast cancer. Hence for purposes of applying art, Examiner is broadly considering that any art that teaches the active recited steps inherently teaches a method for predicting a response of a patient to a treatment for breast cancer.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as lacking a correspondence between preamble and the recited steps that comprise the method.

The preamble of claim 1 states it's a method for predicting a response of a patient to a

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treatment for breast cancer. The active steps that follow recite how presence of an amplicon is detected. However none of these steps recite the connection between detection of an amplicon with the recited preamble namely predicting a response of a patient to a treatment for breast cancer. So it is not clear to one of ordinary skill how the claimed method is to be performed so as to achieve the desired end i.e. predicting a response of a patient to a treatment for breast cancer.

Claims 2-9 depend from claim 1 and hence share the same problem.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by de Sauvage et al. (US Pat. 7,285,382 B2 issued October 2007 with priority back to Jan 2000).

Regarding claim 1, de Sauvage et al. teach a method for predicting a response of a patient to a treatment for breast cancer (see claim interpretation above. Also see title where treatment of cancer is taught. See col. 2 lines 33-36 where response of treatment of a breast cancer patient to combination of paclitaxel and doxorubicin is taught), comprising the following stages:

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A - extracting the nuclear material from a biological specimen (see col. 67 line 19 where genomic library is taught, thus by teaching genomic library de Sauvage et al. inherently teach extracting the nuclear material from a biological specimen which in turn is used to make the genomic library. Also see col. 68 line 63 where genomic DNA is taught. Thus de Sauvage et al. inherently teach extracting the nuclear material from a biological specimen to obtain genomic DNA),

B - obtaining amplicons of at least one target sequence of the nuclear material with at least one pair of amplification primers (see col. 74 line 44 where PCR amplification is taught. Thus by teaching PCR amplification de Sauvage et al. inherently teach obtaining amplicons of at least one target sequence of the nuclear material with at least one pair of amplification primers. Also see col. 73 line 59-60 where PCR amplification with primers complementary to the 5' and 3' regions are taught, thus teaching obtaining amplicons of at least one target sequence of the nuclear material with at least one pair of amplification primers), and

C - detecting the presence of said amplicons with at least one detection probe (see col. 93 line 50-51 where PCR generated labeled riboprobes are taught as detection probe. Also see col. 97-98 Table 4 where by using the labeled probe detection of LIV-1 in various tissues is taught. Thus teaching the presence of said amplicons with at least one detection probe)

wherein said pair of primers comprises at least one amplification primer comprising at least 15 nucleotide motifs of a nucleotide sequence selected from SEQ ID No. 1 to SEQ ID No. 20 (Applicant has elected SEQ ID NO 7 and SEQ ID NO 8 as pair

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of amplification primers. See alignment below where 100% match is found between the primer of SEQ ID NO: 7 and nt 615 to 596 of SEQ ID NO: 15 taught by de Sauvage et al.

SEQ ID NO: 7

```

RESULT 11
EA301547/c
LOCUS      EA301547                      620 bp      DNA      linear      PAT 14-DEC-
2007
DEFINITION Sequence 15 from patent US 7285382.
ACCESSION  EA301547
VERSION    EA301547.1  GI:162438418
KEYWORDS   .
SOURCE     Unknown.
  ORGANISM Unknown.
            Unclassified.
REFERENCE  1  (bases 1 to 620)
  AUTHORS  de Sauvage,F., Goddard,A., Gurney,A.L., Hongo,J.-A.S. and
Smith,V.
  TITLE    Compositions and methods for treatment of cancer
  JOURNAL  Patent: US 7285382-A 15 23-OCT-2007;
            Genentech, Inc.; South San Francisco, CA;
            US;
FEATURES   Location/Qualifiers
    source  1..620
            /organism="unknown"
            /mol_type="genomic DNA"
ORIGIN

```

```

Query Match      100.0%;  Score 20;  DB 2;  Length 620;
Best Local Similarity 100.0%;  Pred. No. 17;
Matches 20;  Conservative 0;  Mismatches 0;  Indels 0;  Gaps
0;

```

```

Qy      1 GAGCCAGCCC GAAGTCTGTA 20  SEQ ID NO: 7
          |||||
Db      615 GAGCCAGCCC GAAGTCTGTA 596 SEQ ID NO: 15

```

See alignment below where 100% match is found between the primer of SEQ ID NO: 8 and nt 430 to 450 of SEQ ID NO: 15 taught by de Sauvage et al.

SEQ ID NO: 8

```

RESULT 10
EA301547

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```

LOCUS       EA301547                620 bp    DNA        linear        PAT 14-DEC-
2007
DEFINITION   Sequence 15 from patent US 7285382.
ACCESSION    EA301547
VERSION      EA301547.1   GI:162438418
KEYWORDS     .
SOURCE       Unknown.
  ORGANISM   Unknown.
             Unclassified.
REFERENCE    1   (bases 1 to 620)
  AUTHORS    de Sauvage,F., Goddard,A., Gurney,A.L., Hongo,J.-A.S. and
Smith,V.
  TITLE      Compositions and methods for treatment of cancer
  JOURNAL    Patent: US 7285382-A 15 23-OCT-2007;
             Genentech, Inc.; South San Francisco, CA;
             US;
FEATURES             Location/Qualifiers
     source          1..620
                     /organism="unknown"
                     /mol_type="genomic DNA"
ORIGIN
Query Match          100.0%;   Score 21;   DB 2;   Length 620;
Best Local Similarity 100.0%;   Pred. No. 9.9;
Matches    21;   Conservative    0;   Mismatches    0;   Indels    0;   Gaps
0;

Qy              1  TCTTAGACCATGTCCGGGAAA 21   SEQ ID NO: 8
                |||||||||||||||||||
Db             430 TCTTAGACCATGTCCGGGAAA 450 SEQ ID NO: 15

```

Thus by teaching 100% match to elected primers of SEQ ID NO 7 and 8 de
Sauvage et al. teach wherein said pair of primers comprises at least one amplification
primer comprising at least 15 nucleotide motifs of a nucleotide sequence selected from
SEQ ID No. 1 to SEQ ID No. 20

and/or,

said detection probe comprises at least 15 nucleotide motifs of a nucleotide sequence selected from SEQ ID No. 1 to SEQ ID No. 20. See alignment below where 100% match of the elected probe sequence of SEQ ID NO 12 to nt 521 to 540 of SEQ ID NO 15 taught by de Sauvage et al. is shown.

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SEQ ID NO: 12

```

RESULT 14
EA301547
LOCUS      EA301547                620 bp    DNA        linear    PAT 14-DEC-
2007
DEFINITION Sequence 15 from patent US 7285382.
ACCESSION  EA301547
VERSION    EA301547.1  GI:162438418
KEYWORDS   .
SOURCE     Unknown.
  ORGANISM Unknown.
            Unclassified.
REFERENCE  1  (bases 1 to 620)
  AUTHORS  de Sauvage,F., Goddard,A., Gurney,A.L., Hongo,J.-A.S. and
Smith,V.
  TITLE    Compositions and methods for treatment of cancer
  JOURNAL   Patent: US 7285382-A 15 23-OCT-2007;
            Genentech, Inc.; South San Francisco, CA;
            US;
FEATURES   Location/Qualifiers
  source    1..620
            /organism="unknown"
            /mol_type="genomic DNA"
ORIGIN
    Query Match      100.0%;  Score 20;  DB 2;  Length 620;
    Best Local Similarity 100.0%;  Pred. No. 0.017;
    Matches 20;  Conservative 0;  Mismatches 0;  Indels 0;  Gaps
0;
QY          1 GGAGGATGTGCGGCTCGTAC 20  SEQ ID NO: 12
            |||||
Db          521 GGAGGATGTGCGGCTCGTAC 540 SEQ ID NO: 15

```

The primers of SEQ ID 7 and 8 will amplify sequence of ErbB2 (also known as HER2—see col. 99 line 60) taught by de Sauvage et al. The probe of SEQ ID NO 12 falls in the middle of the amplicon that will be amplified using primer pairs of SEQ ID NO 7 and 8.

Thus de Sauvage et al. teach all the active steps recited in the instant claim 1.

Regarding claim 2, de Sauvage et al. teach wherein said pair of primers is selected from the group consisting of: a first amplification primer comprising at least 15

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nucleotide motifs of nucleotide sequence SEQ ID No. 7 and a second amplification primer comprising at least 15 nucleotide motifs of nucleotide sequence SEQ ID No. 8 (see claim 1 above where these two are shown);

Regarding claim 3, de Sauvage et al. teach wherein said pair of primers comprises at least one amplification primer comprising a promoter permitting the initiation of transcription by a polymerase of bacteriophage T7 (see col. 96 line 29 and 30 where T7 promoter is taught. Thus by teaching T7 promoter de Sauvage et al. teach wherein said pair of primers comprises at least one amplification primer comprising a promoter permitting the initiation of transcription by a polymerase of bacteriophage T7).

Regarding claim 5, de Sauvage et al. teach wherein the target sequence comprises a gene selected from the group consisting of ESR1, ESR2, PGR, and HER2 (Applicant has elected HER2 for examination--See col. 1 line 45 where HER2 is taught).

Regarding claim 7, de Sauvage et al. teach wherein a second pair of amplification primers is used to obtain amplicons specific to a housekeeping gene (see col. 96 line 2 where β -actin is taught as control gene. Also see col. 96 lines 34-43 where sequence of template for transcribing β -actin is provided. Thus de Sauvage et al. teach wherein a second pair of amplification primers is used to obtain amplicons specific to a housekeeping gene).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Sauvage et al. as applied to claim 7 above, and further in view of Spik et al. (1991) J. Biol. Chem. 266 917): pp10735-10738.

Regarding claim 8, de Sauvage et al. teach method of claim 7, but do not explicitly teach wherein one of the amplification primers for obtaining amplicons specific to a housekeeping gene comprises at least 15 nucleotide motifs of a sequence selected from SEQ ID No. 25 to 29.

Regarding claim 8, Spik et al. teach wherein one of the amplification primers for obtaining amplicons specific to a housekeeping gene comprises at least 15 nucleotide motifs of a sequence selected from SEQ ID No. 25 to 29 (See page 10736 Fig. 2 nt 264 to 283 of SCYLP sequence correspond to nt 1-20 of primer recited as SEQ ID 28 in instant application. See alignment below:

RESULT 1
264to283

Query Match 100.0%; Score 105; DB 1; Length 20;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 20; Conservative 0; Mismatches 0; Indels 0; Gaps
0;

Qy 1 AGGAGAGAAAGGATTTGGCT 20 SEQ ID NO 28
| | | | | | | | | | | | | | | | | | | | | |
Db 1 AGGAGAGAAAGGATTTGGCT 20 Region of SCYLP sequence (nt 264-283)

Thus by teaching a 100% match to a 20 mer region comprised in a bigger region Spik et al. teach wherein one of the amplification primers for obtaining amplicons specific to a housekeeping gene comprises at least 15 nucleotide motifs of SEQ ID No. 28.

Regarding claim 9, Spik et al. teach first amplification primer comprising at least 15 nucleotide motifs of nucleotide sequence SEQ ID No. 27 (page 10736 Fig. 2 nt 503 to 482 of SCYLP sequence correspond to nt 1-22 of primer recited as SEQ ID 27 in instant application. See alignment below

RESULT 1
482to503/c

```
Query Match          100.0%;  Score 134;  DB 2;  Length 22;
Best Local Similarity 100.0%;  Pred. No. 0;
Matches   22;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

QY          1 CAGGCTGTCTTGACTGTCGTGA 22 SEQ ID 27
              |||||
Db          22 CAGGCTGTCTTGACTGTCGTGA 1  Region of SCYLP
```

Thus by teaching a 100% match to a 22 mer region comprised in a bigger region Spik et al. teach first amplification primer comprising at least 15 nucleotide motifs of nucleotide sequence SEQ ID No. 27

Regarding claim 9, Spik et al. teach a second amplification primer comprising at least 15 nucleotide motifs of nucleotide sequence SEQ ID No. 28. See details provided above for location on SCYLP sequence where SEQ ID NO 28 binds.

Thus primer of SEQ ID NO 28 will act as upstream 5' end primer and primer of SEQ ID NO 27 will act as downstream 3' end primer to amplify ~240 bp amplicon from the SCYLP sequence.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to design primers using the SCYLP gene sequence taught by Spik et al. to amplify a housekeeping gene. SCYLP is a gene whose product is expressed in human milk. In other words this gene SCYLP is expressed in mammary

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tissue. One of ordinary skill in the art is taught by Spik et al. that the central part of the SCYLP molecule corresponds to highly conserved part of the amino acids (see page 10737 col. 2 top 4 lines). Hence one of ordinary skill in the art has a reasonable expectation of success in being able to amplify a ~240 bp amplicon using the above two primers which are designed from the conserved region of SCYLP gene. Since breast cancer cells are also derived from mammary tissue, the choice of a housekeeping gene that is also expressed in mammary tissue provides for a good internal control.

14. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Sauvage et al. as applied to claim 1 above, and further in view of Konigshoff et al. (February 2003) Clinical Chemistry 49:2 pages 219-229.

Regarding claim 4, de Sauvage et al. teach method of claim 1 and use of labeled probe, but do not teach wherein the detection probe comprises a flurophore and a quencher.

Regarding claim 4, Konigshoff et al. teach wherein the detection probe comprises a flurophore and a quencher (see page 221 table 1 where FAM and LCred 640 pairs are taught as flurophore and a quencher pairs to label detection probes referred to a up and down probes. Thus Konigshoff et al. teach wherein the detection probe comprises a flurophore and a quencher)

Regarding claim 6, Konigshoff et al. teach wherein stages B and C are carried out simultaneously (see page 225 par. 3 where quantitative real time PCR is taught. by teaching real time PCR Konigshoff et al. inherently teach wherein stages B and C are carried out simultaneously).

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to practice the method of Konigshoff et al. in the method of de Sauvage et al. The motivation to do so is provided to one of ordinary skill in the art by teachings of Konigshoff et al. who state "For real-time PCR, DNA concentrations of as low as 4 ng per 10- μ l reaction are sufficient. This amount corresponds to ~ 1330 copies of a single copy gene such as *HER-2/neu* or *IGF-1*. It is a major advantage of this protocol that small amounts of material are sufficient because, in clinical practice, frequently only limited amounts of sample are available (e.g., microdissected samples), which must be used for several different analyses" (see page 226 par. 4). Thus based on teachings of Konigshoff et al. one of ordinary skill is motivated to practice the method of Konigshoff et al. in the method of de Sauvage et al and has a reasonable expectation of success in being able to successfully perform real time detection of the HER2 gene and the chosen internal control gene using small amount of clinical material as the starting point. Thus allowing for an exhaustive array of analyses to is performed using the precious biopsy material obtained from the cancer patient.

Conclusion

15. All claims under consideration 1-9 are rejected over prior art.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUCHIRA PANDE whose telephone number is (571)272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637

/Suchira Pande/
Examiner, Art Unit 1637